

**EPA Reg. No. 86004-3 vol. 2 part 2**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

1-3-14

Bhushan Mandava  
Mandava Associates, LLC  
1050 Connecticut Ave. NW  
Suite 1000  
Washington, DC 20036

Subject: EPA Reg. 86004-3/ Glycel 41% SL Notification

Dear Mr. Mandava:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 1-22-14 for the product EPA Reg. 86004-3/ Glycel 41% SL. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action doesn't fall within the scope of PRN 98-10. The alternate csf #3 is not acceptable. The csf states that the AI content of EPA Reg. 86004-1 is 96.5% and this is incorrect (the correct amount is 97.3%). The amounts for [REDACTED] and the amount for [REDACTED] You are only allowed to list alternate sources on the same csf if the AI% is the same (for example you may list 2 alternate sources if both are 97.3%). You should also revise you basic csf because the AI% for EPA Reg. 86004-1 is incorrect on that csf as well.

If you have any questions please call Erik Kraft at 703-308-9358 or email at [Kraft.Erik@epa.gov](mailto:Kraft.Erik@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Bo Davis", is written over a horizontal line.

Kable "Bo" Davis  
Product Manager 25  
Herbicide Branch  
Registration Division (7505P)

# MANDAVA ASSOCIATES, LLC

CONSULTANTS IN SCIENCE, TECHNOLOGY AND REGULATORY AFFAIRS

1050 CONNECTICUT AVENUE, N.W., SUITE 1000, WASHINGTON, DC 20036

TELEPHONE: (202)-223-1424/1747 · TELEFAX: (202)-223-0141 · E-Mail: mandava@compuserve.com

Hand Delivered

January 22, 2014

Mr. Kable Bo Davis  
Product Manager (PM 25)  
Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202-4501

SUBJECT: Product Name: Glycel 41% SL  
EPA Reg. 86004-3  
Notification per PR Notice 98-10 for an alternate source of active ingredient.

Dear Mr. Davis:

On behalf of Repar-Glypho, LLC, enclosed, please find the submission of an alternate sources of active ingredient for Glycel 41% SL, EPA Reg. No. 86004-3. We have prepared the CSF Alternate Formulation #3 to include as an alternate source of Active Ingredient from [REDACTED]

The following materials are submitted in support of the notification:

- 1) Application for Registration (EPA Form 8570-1)
- 2) Formulator's Exemption Form (EPA Form 8570-27)
- 3) Copy of Most Recent Confidential Statement of Formula (CSF) (EPA Form 8570-4)
- 4) Two copies of proposed Confidential Statement of Formula (CSF) (EPA Form 8570-4)

We request the Agency to approve [REDACTED] as alternate source of active ingredient for Glyphosate 41% SL for use in formulation by Repar-Glypho, LLC.

If there are further questions, please contact us at 202-223-1424.

Sincerely,

*N. Bhushan Mandava*

N. Bhushan Mandava, Ph.D., FAC  
Agent for Repar-Glypho, LLC

Attachment

\*Product ingredient source information may be entitled to confidential treatment\*



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 86004-3	2. EPA Product Manager Kable Bo Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Glycel 41% SL	PM# 25	
5. Name and Address of Applicant (Include ZIP Code) Repar-Glypho, LLC 8070 Georgia Avenue, Suite 209 Silver Spring, MD. 20910 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

**Section - II**

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION OF ALTERNATE SOURCE OF ACTIVE INGREDIENT PER PR NOTICE 98-10.

This notification is consistent with the provisions of PR Notice 98-10 and 40 CFR 152.46 and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Please direct all correspondence to: N. Bhushan Mandava Phone No. 202-223-1424 Fax No. 202-223-0141 E-mail: mandava@compuserve.com

**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name N. Bhushan Mandava		Title Agent for Repar-Glypho, LLC	
		Telephone No. (Include Area Code) 202-223-1424	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			
2. Signature <i>N. Bhushan Mandava</i>		3. Title Agent for Repar-Glypho, LLC	
4. Typed Name N. Bhushan Mandava		5. Date January 22, 2014	
6. Date Application Received (Stamped)			



United States  
**Environmental Protection Agency**  
 Washington, DC 20460  
**Formulator's Exemption Statement**  
*(40 CFR 152.85)*

Applicant's Name and Address

Repar-Glypho, LLC  
 8070 Georgia Avenue, Suite 209  
 Silver Spring, MD. 20910

EPA File Symbol/Registration Number  
 86004-3

Product Name  
 Glycel 41% SL

Date of Confidential Statement of Formula (*EPA Form 8570-4*)  
 01/22/2014

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Glyphosate: N-(phosphonomethyl) glycine

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (*EPA FORM 8570-4*) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(*EPA Form 8570-4*) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

**Source**

Active Ingredient	Product Name	Registration Number
Glyphosate: N-(phosphonomethyl) glycine	[REDACTED]	[REDACTED]
Signature <i>N. Blushaw Mandev</i>	Name and Title Agent for Repar-Glypho, LLC	Date 01/22/2014

# Receipt for Section 3

S: 946593

Milestone Email:

Regulatory Type:

Resubmission: ☐ Yes ☒ No

Application Type:

Fee For Service: ☐ Yes ☒ No

[Print Letter](#)

[Enter More Information](#)

[Tracking](#)

Company:  ☒

Risk Manager:

Product #:  Product Name:

Override#:

Me Too

Me Too

Section3:

Product Name:

Application Date:  ☐

OPP Rec'd Date:  ☐

Front End Date:  ☐

Risk Manager Send Date:  ☐

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

NOTIFICATION per PR Notice 98-10

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content	Des
CSF	

[View/Edit](#)

# Material Sent for Data Extraction

Reg. # 86004-3

Description: CSF Amendment

☒ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated \_\_\_\_\_

☐ Notification Dated \_\_\_\_\_

☒ New CSF(s) Dated May 6, 2013

☐ Other: \_\_\_\_\_

☒ Decision #: 476721

☐ Other Action/Comments: \_\_\_\_\_

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Emily Hartman

Phone: 347-0189 Division: RD/HB

Date: July 10, 2013



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

N. Bhushan Mandava, Ph.D.  
Repar-Glypho, LLC  
8070 Georgia Avenue  
Suite 209  
Silver Spring, MD 20910

JUL 10 2013

Subject: Confidential Statement of Formula (CSF) Amendment – Adding New Source  
Product Name: Glycel 41% SL  
EPA Registration Number: 86004-3  
Application Date: March 18, 2013  
Decision Number: 476721

Dear Dr. Mandava,

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is, as amended, acceptable.

The Confidential Statement of Formula dated May 6, 2013 for the alternate formulation (alternate #2) is acceptable and has been added to your record. Two associated Agency reviews are attached (DP 412867, DP 411225).

If you have any questions, please call me directly at (703) 306-0415 or Emily Hartman of my staff at (703) 347-0189.

Sincerely,

A handwritten signature in black ink, appearing to read "Kable Bo Davis", enclosed within a large, loopy oval.

Kable Bo Davis, Product Manager 25  
Herbicide Branch  
Registration Division  
Office of Pesticide Programs

Enclosure





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

FEE

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

DP BAR CODE NO.: 411225  
PC Code(s): 103601  
FOOD Use: Yes

EPA Reg. NO.: 86004-3 DECISION NO.: 476721  
ACTION CODE: R340

DATE OUT: May 7, 2013

SUBJECT: End Use Product Chemistry Review  
Product Name: Glycel 41% SL

FROM: Hari Mukhoty  
Product Chemistry Team  
Technical Review Branch / Registration Division (7505P)

TO: Emily Hartman, RMR / Kable Davis, RM - 25  
Herbicide Branch / Registration Division (7505P)

Company Name: Repar – Glypho, LLC.  
Formulation Type: Not provided.

**INTRODUCTION:**

The registrant has re-submitted one amended CSF [Alt. # 2 / Dated: 05/06/2013] to the above mentioned basic for the registration of the aforesaid product under EPA Reg. No. 86004-3. The registrant submitted product chemistry Group A data under MRID: 490848-01.

The proposed alternate formulation (2) is very similar to the accepted basic product except that alt # 2 is produced in China whereas the basic product is manufactured in Silver Spring, MD in USA. Additionally, in the accepted basic formulation the source of the active ingredient has been stated to be 95.0% in EPA Reg. No. 86004-1. However, actually as per EPA record the purity of the source is 97.3% which has been used in the proposed alternate formulation to calculate the nominal concentration of the active ingredient.

TRB has been requested to evaluate the product chemistry data required for registration of the proposed alternate formulation # 2.

**SUMMARY OF FINDINGS:**

1. Name of Active Ingredient(s): Glyphosate-Isopropylamine salt (41.0%).
2. Has the registrant claimed substantial similarity to registered product?  
[ ] Yes [X] No [ ] NA If yes: EPA Reg. No.
3. The source material(s) of the active ingredient(s) is/are registered with the Agency.
4. All inert ingredients have been approved by IIAB on 3/25/2013 for food uses (Pre-Harvest Application to Growing Crops).
5. The CSF of the proposed alternate formulation (# 2) has been filled out completely and correctly.

DP BAR CODE NO.: 411225

PC Code(s): 103601

FOOD Use: Yes

EPA Reg. NO.: 86004-3 DECISION NO.: 476721

ACTION CODE: R340

6. Confidential Statement of Formula(s):

☐ Basic -

Dated: NA

re-submitted – Dated: NA

☒ Alternate

Dated: 03/18/2013

re-submitted – Dated: 05/06/2013

Alternate CSF(s) complies with 40CFR §152.43: ☒ Yes ☐ No NA ☐.

7. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concur with product label (PR Notice 91-2)

☒ Yes

Is the sub statement in compliance with PR Notice 97-6?

☒ Yes ☐ No - Uses the term "Other Ingredients"  
, if not, explain below:

Metallic equivalent:

☐ Yes ☒ NA;

Soluble arsenic:

☐ Yes ☒ NA

Isomeric ratios:

☐ Yes ☒ NA

Acid equivalent:

☐ Yes ☒ Yes 3 pounds of per us gallons of the acid, glyphosate

b. Health related sub statements:

Petroleum distillate at > 10%: ☐ Yes ☐ No ☒ NA

Methanol at > 4%: ☐ Yes ☐ No ☒ NA

Sodium Nitrate / Sodium Nitrite ☐ Yes ☐ No ☒ NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown? Flash Point NA

☐ Yes ☒ No The label contains a Physical or chemical hazard statement for containers for mixing, storing and applying for the product.

Total Release Fogger PR Notice 98-6 (40 CFR 156.78 d): ☐ Yes ☐ No ☒ NA

d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No

Final decision of overall label acceptance will be made by the PM.

DP BAR CODE NO.: 411225  
PC Code(s): 103601  
FOOD Use: Yes

EPA Reg. NO.: 86004-3 DECISION NO.: 476721  
ACTION CODE: R340

8. Group A: Product Chemistry Data

TRB's determination of the acceptability of the data for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos. 490848-01
			Yes	No		
830.1550	Product Identity & Composition		X		A	"
830.1600	Description of materials used to produce the product		X		A	"
830.1650	Description of formulation process		X		A	"
830.1670	Discussion on the formation of impurities		X		A	"
830.1700	Preliminary analysis			X	NA	" As stated in CSF dated: 05/06/2013
830.1750	Certified limits (158.350)	Standard certified Limits	X		A	
		Justification for wider limits				
830.1800	Enforcement analytical method #		X		N	"

A = Acceptance, N = Not Acceptable, G = Data Gap,  
W = Waiver Request, I = In Progress, NA = Not Applicable  
# Analytical Method: HPLC using UV- Spectrophotometric Method detector set at 243 nm. Validation was not performed for accuracy, precision and linearity.

DP BAR CODE NO.: 411225  
PC Code(s): 103601  
FOOD Use: Yes

EPA Reg. NO.: 86004-3 DECISION NO.: 476721  
ACTION CODE: R340

**CONCLUSIONS:**

1. TRB has reviewed the re-submitted CSF (dated: 05/06/2013) for the proposed alternation formulation (# 2) and has found it to be acceptable. The CSF is attached with this review and could be located in OPPIN CHEM DOCS.
2. Product chemistry Group A data, with the exception of Enforcement Analytical Method (830.1800) are satisfied and acceptable. Group B data are not required for alternate formulation.
3. The proposed label was screened as it pertains to the product chemistry requirements. The PM should get the "Formulation Type" from the registrant. The preferred site of insertion of Formulation Type would be on the proposed label under "Direction to Use". The final review of the proposed label and uses are the purview of the PM team.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

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OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

DP BAR CODE NO.: 412867  
PC Code(s): 103601  
FOOD Use: Yes

EPA Reg. NO.: 86004-3 DECISION NO.: 476721  
ACTION CODE: R340

DATE OUT: July 3, 2013

SUBJECT: End Use Product Chemistry Review  
Product Name: Glycel 41% SL

FROM: Hari Mukhoty  
Product Chemistry Team  
Technical Review Branch / Registration Division (7505P)

TO: Emily Hartman, RMR / Kable Davis, RM - 25  
Herbicide Branch / Registration Division (7505P)

Company Name: Repar – Glypho, LLC.  
Formulation Type: Not provided.

**INTRODUCTION:**

The registrant has submitted the validation data of the Enforcement analytical method used to quantify the concentration of the active ingredient used in the amended CSF [Alt. # 2 / Dated: 05/06/2013] to the above mentioned basic for the registration of the aforesaid product under EPA Reg. No. 86004-3. The registrant previously submitted product chemistry Group A data, with the exception of validation data, under MRID: 490848-01.

TRB has been requested to evaluate the validation data submitted for registration of the proposed alternate formulation # 2.

**SUMMARY OF FINDINGS:**

1. The validation data were provided in a letter dated July 1, 2013 and is attached with this review.
2. The complete product chemistry data, except validation data, for the proposed alternate formulation # 2 were reviewed on 05/07/2013.

DP BAR CODE NO.: 412867  
PC Code(s): 103601  
FOOD Use: Yes

EPA Reg. NO.: 86004-3 DECISION NO.: 476721  
ACTION CODE: R340

**CONCLUSIONS:**

1. TRB has reviewed and accepted the validation data.
2. Product chemistry Group A data are satisfied and acceptable. Group B data are not required for alternate formulation.

**MANDAVA ASSOCIATES, LLC**

**CONSULTANTS IN SCIENCE, TECHNOLOGY AND REGULATORY AFFAIRS**  
**1050 CONNECTICUT AVENUE, N.W., SUITE 1000, WASHINGTON, DC 20036**

Telephone: (202)-223-1424/1747 · Fax: (202)-223-0141 · E-MAIL: [Mandava@compuserve.com](mailto:Mandava@compuserve.com)

Hand Delivered

March 18, 2013

Mr. Kable Bo Davis  
 Product Manager (PM 25)  
 Herbicide Branch  
 Registration Division (7504C)  
 Office of Pesticide Programs  
 U.S. Environmental Protection Agency  
 Washington, D.C. 20460

SUBJECT: Alternate Source for GLYCEL 41 % SL  
 Active Ingredient: Glyphosate  
 Registrant: Repar-Glypho, LLC  
 EPA Reg. No.: 86004-3

PRIA Category: R340, PRIA FEE: \$904.25

Dear Mr. Davis:

Glycel 41 % SL (EPA Reg. No.: 86004-3) is registered by Repar Glypho, LLC as an end-use product containing Glyphosate as an active ingredient (AI). The source for AI is Glyphosate Technical (EPA Reg. No: 86004-1).

The registrant (Repar Glypho, LLC) is seeking an alternative source for g Glycel 41 % SL and the producer for proposed alternate source is [REDACTED]

On behalf of Repar-Glypho, LLC, we are submitting the Product Chemistry data in support of a **ME-TOO** application for the registration of GLYCEL 41 % SL.

In support of the alternate source for Glycel 41 % SL, we are providing the following administrative materials.

- 1) Application for Pesticide Registration (EPA Form 8570-1)
- 2) Registration Fee Waiver Payment (Agency Tracking ID: 74424291698)
- 3) Confidential Statement of Formula (EPA Form 8570-4)
- 4) Certification with Respect to Citation of Data (EPA Form 8570-34)
- 5) Data Matrix (EPA Form 8570 – 35)

\*Product ingredient source information may be entitled to confidential treatment\*

Mr. Kable Bo Davis (PM 25)  
March 18, 2013

Page 2

We are also submitting the product chemistry data in support of the alternate source for Glycel 41 % SL:

**Volume12: GLYCEL 41% SL:** Product Properties Data in Support of FIFRA Registration; Data Requirement: 40 CFR 158.300-355; OPPTS Series 830 (Project No.: REPAR-GLYPHO41SL-16); Repar-Glypho, LLC.

We have enclosed a copy of the approved label for Glycel 41% SL (EPA Reg. No. 86004-3).

Please also note that Repar-Glypho, LLC is relying on the safety data submitted by other registrants on Glyphosate.

In addition to the above studies, we are also relying on other items of data on the subject product in the Agency's files.

We are requesting an "**Expedited Review**" in accordance with FIFRA Section 3(c)(3)(b)(i), because we unequivocally showed that, based on the product chemistry data, the proposed alternate source for Glycel 41% SL is the same as or substantially similar to the registered Glycel 41% SL (EPA Reg. No.: 86004-3), we request you to approve the proposed alternate source (alternate formulation #2).

Thank you for your ready cooperation.

Sincerely,



N. Bhushan Mandava, Ph.D., RAC  
Agent for Repar-Glypho, LLC

Enclosure



TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Repar-Glypho, LLC  
c/o Mandava Associates, LLC  
1050 Connecticut Avenue, NW / Suite 1000  
Washington, DC 20036

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

FIFRA Registration Application for:

Product Name:	Glycel 41% SL
Active Ingredient:	Glyphosate
EPA Company No.:	86004
EPA Reg. No.:	86004-3

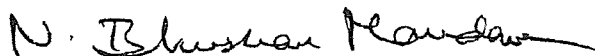
TRANSMITTAL DATE:

March 18, 2013

LIST OF SUBMITTED STUDIES:

49084801 **Volume12:** **GLYCEL 41% SL:** Product Properties Data in Support of FIFRA Registration; Data Requirement: 40 CFR 158.300-355; OPPTS Series 830 (Project No.: REPAR-GLYPHO41SL-16); Repar-Glypho, LLC.

COMPANY OFFICIAL:



N. Bhushan Mandava  
Registration Agent for Repar-Glypho, LLC

COMPANY CONTACT:

N. Bhushan Mandava  
Mandava Associates, LLC  
1050 Connecticut Avenue, NW/Suite 1000  
Washington, D.C. 20036  
(202) 223-1424/1747

# **MANDAVA ASSOCIATES, LLC**

CONSULTANTS IN SCIENCE, TECHNOLOGY AND REGULATORY AFFAIRS

1050 CONNECTICUT AVENUE, N.W., SUITE 1000, WASHINGTON, DC 20036

Telephone: (202)-223-1424/1747 □ Fax: (202)-223-0141 □ E-MAIL: [Mandava@compuserve.com](mailto:Mandava@compuserve.com)

## **HAND DELIVERED**

July 1, 2013

Kable Bo Davis  
Product Manager 25  
Herbicide Branch  
Registration Division (7505P)  
U.S. Environmental Protection Agency  
Washington, DC 20460

SUBJECT: Incomplete Application - Data Deficiency  
Product: Glycel 41%  
EPA Reg. No.: 86004-3  
Decision No.: 476721

Response to Your letter dated May 30, 2013

Dear Mr. Mandava:

This is in response to your May 30, 2013 letter and an e-mail communication dated June 3, 2013 from Emily Hartman of your team concerning the Agency letter and review regarding the alternate source for Glycel 41% SL (EPA Reg. No. 86004-3).

### **Re. Data Deficiency**

It is our understanding that the Agency identified one deficiency based on the review of the product chemistry data. This deficiency is for enforcement analytical method (OCSPP 830.1800) which requires data on validated analytical method for alternate source for Glycel 41% SL (EPA Reg. No. 86004-3).

Previously, the registrant submitted the High Performance Liquid Chromatography (HPLC) as the analytical method (see pages 16-18 of 25 of 25 in Product Chemistry Data for Glycel 41% SL; MRID 490848-01). According to Agency's review (DP Bar Code: 411225; Date: May 7, 2013), the details regarding the validation of the method are not provided. This is the only deficiency.

### **Re. Method Validation**

The supplier for alternate source of glyphosate is [REDACTED]  
[REDACTED] which provided the following information on method validation.

Glycel 41% SL (EPA Reg. No.: 86004-3) is the brand name for 41% glyphosate-Isopropylamine (IPA) salt. The active ingredient (a.i) is calculated as glyphosate acid.

The registrant has already provided the information on the enforcement analytical method which is HPLC method (see pages 16-18 of 25 in Product Chemistry Data for Glycel 41% SL; MRID 490848-01).

The following additional information is provided for method validation which includes the accuracy and precision. As you will notice (see tables below, the method accuracy is 98.96%.

#### Accuracy

No.	The known quantity (mg)	The addition quantity (mg)	The measured quantity (mg)	Recovery (%)	The average recovery (%)
1	31.78	50.00	81.12	98.68	98.96
2	40.84	50.00	90.34	99.00	
3	50.88	50.00	100.25	98.74	
4	61.02	50.00	110.63	99.22	
5	71.54	50.00	121.11	99.14	

#### 2. Precision

Component	The measured results (%)					Average (%)	Standard deviation	C.V. (%)
glyphosate	30.3	30.4	30.1	30.4	30.5	30.3	0.16	0.53

The typical HPLC chromatographic profiles for glyphosate standard and Glycel 41% SL (same as Glyphosate 41% SL) sample are also included (See Figures 1 and 2).

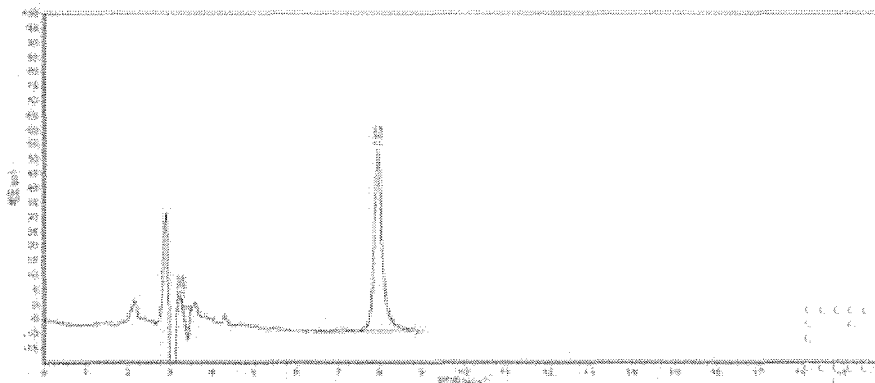


Figure 1. Chromatogram of glyphosate standard

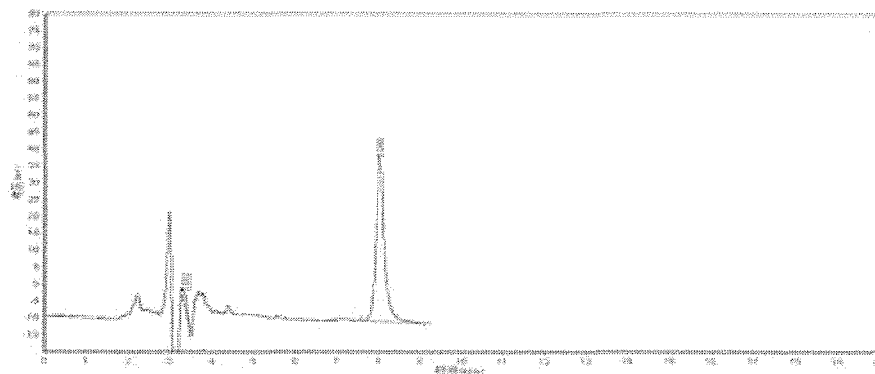


Figure 2. Chromatogram of glyphosate 41% SL sample

### Conclusion

The above-mentioned information will satisfy the deficiency in product chemistry data for enforcement analytical method (OCSP 830.1800) for alternate source for Glycel 41% SL (EPA Reg. No. 86004-3).

If there are further questions, please contact me at 202-223-1424.

Sincerely,

*N. Bhushan Mandava*

N. Bhushan Mandava, Ph.D.  
Agent for Repar Corporation

Cc. Emily Hartman



United States  
Environmental Protection Agency  
Washington, DC 20460

☐  
☐  
☒

Registration  
Amendment  
Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 86004-3	2. EPA Product Manager Kable Bo Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Glycel 41% SL	PM# 25	
5. Name and Address of Applicant (Include ZIP Code) Repar-Glypho, LLC 8070 Georgia Avenue, Suite 209 Silver Spring, MD 20910 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

- 1) This application is for the approval of alternate source of Repar-Glypho, LLC for Glycel 41% SL (EPA Reg. No. 86004-3).
- 2) Submittal of Product Chemistry data on Glycel 41% SL which is proposed to be used as the alternate source.
- 3) PRIA Category: R 340. Submitted Fee: \$904.25. Fee Waiver Request
- 4) Please direct all correspondence to: Mandava Associates, LLC; 1050 Connecticut Avenue, NW / Suite 1000; Washington, D.C. 20036.
- 5) The contact person fax number is (202) 223 - 0141 and e-mail address is: mandava@compuserve.com.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name N. Bhushan Mandava	Title Agent for Repar-Glypho, LLC	Telephone No. (Include Area Code) 202-223-1424
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent for Repar-Glypho, LLC	
4. Typed Name N. Bhushan Mandava	5. Date March 18, 2013	



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Repar-Glypho, LLC, 8070 Georgia Avenue, Suite 209, Silver Spring, MD 20910; (202) 223-1424	EPA Registration Number/File Symbol 86004-3
Active Ingredient(s) and/or representative test compound(s) Glyphosate (CAS # 1071-83-6)	Date March 18, 2013
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Herbicide, Terrestrial, Food Crops	Product Name Glycel 41% SL

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT** (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>N. Bhushan Mandava</i>	Date March 18, 2013	Typed or Printed Name and Title N. Bhushan Mandava, Agent for Repar-Glypho, LLC
--	------------------------	--

# PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date: 3-20-13 3/23/09

Experts In-Processing Signature: B. R. Date 3-25-13 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>86004-3</u>		EPA Receipt Date: <u>3-20-13</u>				
Items for Review				Yes	No	N/A*
1	<b>Application Form</b> (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	<b>Confidential Statement of Formula</b> all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to <a href="http://www.epa.gov/opprd001/inerts/">http://www.epa.gov/opprd001/inerts/</a> ), including fragrances, approved for the proposed uses (see Footnote A)			yes X	no 	
3	<b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent					
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)			yes 	no 	
	If applicable, is there a letter of Authorization for exclusive use only.					
4	<b>Formulator's Exemption Statement</b> (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	<b>Data Matrix</b> (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)			yes X	no 	
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	<b>5 Copies of Label</b> (link to <a href="http://www.epa.gov/oppfead1/labeling/lrm/">http://www.epa.gov/oppfead1/labeling/lrm/</a> ) (Electronic labels on CD are encouraged and guidance is available)( link to <a href="http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels">http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels</a> )			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to <a href="http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm">http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm</a> ) included with petitions (link to <a href="http://www.epa.gov/pesticides/regulating/tolerances.htm">http://www.epa.gov/pesticides/regulating/tolerances.htm</a> )			X
9	If applicable for conventional applications, reduced risk rationale (link to <a href="http://www.epa.gov/opprd001/workplan/reducedrisk.html">http://www.epa.gov/opprd001/workplan/reducedrisk.html</a> )			X
10	Required Data (link to <a href="http://www.epa.gov/pesticides/regulating/data_requirements.htm">http://www.epa.gov/pesticides/regulating/data_requirements.htm</a> ) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			



**Comments:**

Inerts approved for food use under 40 CFR 180.90,  
Pre-harvest application to growing crops.  
Passed 11-3 review, MRID 490848

JD 3/25/13

\* N/A – Not Applicable

**Footnotes**

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to [http://www.epa.gov/oppbppd1/biopesticides/contacts\\_bppd.htm](http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm)].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

### **Unapproved Inerts Identified on CSFs**

#### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

March 22, 2013

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-476721  
EPA File Symbol or Registration Number: 86004-3  
Product Name: GLYCEL 41% SL  
EPA Receipt Date: 20-Mar-2013  
EPA Company Number: 86004  
Company Name: REPAR-GLYPHO, LLC

N. BHUSHAN MANDAVA, PH.D.  
MANDAVA ASSOCIATES, LLC  
REPAR-GLYPHO, LLC  
1050 CONN. AVE., NW, STE 1000  
WASHINGTON, DC 20036-

SUBJECT: Receipt of Amendment and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your amendment, 75% small business waiver request, and certification of payment. If you submitted data with this amendment, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R340  
AMENDMENT;NON-FAST TRACK;REVIEW WITHIN RD, E.G. PRECAUTIONARY LABELING;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "Jhe" or similar, is written over the word "Sincerely,".

Front End Processing Staff  
Information Technology & Resources Management Division

# Fee for Service

{932674<~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies? ☒ Fee Waiver?

☐ volpay % Reduction: \_\_\_\_\_

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 25

Receipt No.

S-

932674

EPA File Symbol/Reg. No.

86004-3

Pin-Punch Date:

3/20/2013

☐ This item is NOT subject to FFS action.

## Action Code:

Requested: R340

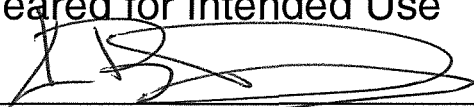
Granted: R340

Amount Due: \$ 3,617.<sup>00</sup>

## Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: 

Date: 3-22-13

Remarks:

**From:** paygovadmin@mail.doc.twai.gov  
**Sent:** Monday, March 18, 2013 3:59 PM  
**To:** Srinivas Mandava, M.D.  
**Subject:** Pay.gov Payment Confirmation: PRIA Service Fees

Application Name: PRIA Service Fees  
Pay.gov Tracking ID: 25A0H35D  
Agency Tracking ID: 74424291698  
Transaction Type: Sale  
Transaction Date: Mar 18, 2013 3:59:09 PM

Account Holder Name: Naga Bhushan Mandava Transaction Amount: \$904.25 Billing Address:  
15404 Tindlay Street  
City: Silver Spring  
State/Province: MD  
Zip/Postal Code: 20905  
Country: USA  
Card Type: AmericanExpress  
Card Number: \*\*\*\*\*4009

Decision Number:  
Registration Number: 3  
Company Name: Repar -Glypho, LLC  
Company Number: 86004  
Action Code: R340

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Figure 1 shows a 10x10 grid of circles representing a 2D lattice. The circles are arranged in a regular pattern, with some circles highlighted in a darker shade to represent occupied sites. The grid is labeled with 'x' and 'y' axes, and the circles are numbered from 1 to 100.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

N. Bhushan Mandava, Ph.D.  
Repar-Glypho, LLC  
c/o Mandava Associates, LLC  
1050 Connecticut Avenue, NW  
Suite 1000  
Washington, DC 20036

MAY 30 2013

Subject: Incomplete Application – Data Deficiency  
Product: Glycel 41% SL  
EPA Registration Number: 86004-3  
Submission Dated: March 18, 2013  
Decision Number: 476721

Dear Dr. Mandava:

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter ending August 12, 2013 to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and



subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time are:

1. The enforcement analytical method requires the submission of method validation data. For more detail, please see the attached Agency review (DP Barcode: 411225).

Further review of your application and your response to the deficiency may identify additional deficiencies and you will be so informed.

FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on [PRIA due date]. Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. **Establish a new due date.** You may work with us to establish a new section 33/PRIA deadline that allows for an appropriate response to the 75 day letter. If you choose this option, you need to contact the Agency not later than July 29, 2013 to discuss a time frame that allows you to address the deficiencies listed above and the Agency to make a regulatory decision.
2. **Withdraw the application.** Alternatively, you may notify us not later than July 29, 2013 that you are withdrawing your application. **As noted above, withdrawal concludes the Agency's review** of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee. Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.
3. **Not respond.** If the Agency does not hear from you by July 29, 2013, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by July 29, 2013 by contacting either Emily Hartman through email

at [hartman.emily@epa.gov](mailto:hartman.emily@epa.gov) or by calling 703-347-0189 or Kable Bo Davis through email at [davis.kable@epa.gov](mailto:davis.kable@epa.gov) or by telephone at 703-306-0415 during the hours of 6:00 am to 3:30 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kable Bo Davis', with a stylized, flowing script.

Kable Bo Davis  
Product Manager (25)  
Herbicide Branch  
Registration Division (7505P)

## Hartman, Emily

---

**From:** Bhushan Mandava [mandava@compuserve.com]  
**Sent:** Monday, July 01, 2013 3:18 PM  
**To:** Hartman, Emily  
**Cc:** Davis, Kable; Srinivas Mandava, M.D.  
**Subject:** FW: Agency Letter and Review (EPA Reg. No. 86004-3)  
**Attachments:** SMANDAVA13070114250.pdf

Dear Ms. Hartman:

This is in response to your June 3, 2013 e-mail concerning the Agency's letter and review regarding the alternate source for Glycel 41% SL (EPA Reg. No. 86004-3).

We have provided the analytical method validation in the attached file and hope that this information will satisfy the deficiency in product chemistry data for enforcement analytical method (OCSPP 830.1800) for alternate source for Glycel 41% SL (EPA Reg. No. : 86004-3).

If there are further questions, please contact me at 202-223-1424.

Sincerely,

N. Bhushan Mandava  
Agent for Repar Corporation  
c/o Mandava Associates, LLC  
1050 Connecticut Avenue, N.W.  
Suite 1000  
Washington, D.C. 20036  
Tel: (202) 223 - 1424  
Fax: (202) 223 -0141

---

**From:** Hartman, Emily [<mailto:Hartman.Emily@epa.gov>]  
**Sent:** Monday, June 03, 2013 8:36 AM  
**To:** Bhushan Mandava  
**Cc:** Davis, Kable  
**Subject:** FW: Agency Letter and Review (EPA Reg. No. 86004-3)

Dear Dr. Mandava,

Could you please confirm receipt of the email below?

Thank you,  
Emily Hartman

---

**From:** Hartman, Emily  
**Sent:** Thursday, May 30, 2013 2:45 PM  
**To:** 'mandava@compuserve.com'  
**Cc:** Davis, Kable  
**Subject:** Agency Letter and Review (EPA Reg. No. 86004-3)

Dear Dr. Mandava,

Attached please find an Agency letter and review regarding the alternate source for Glycel 41% SL (EPA Reg. No. 86004-3).

If you have any questions, please feel free to contact me. Please confirm receipt by replying to this email.

Thank you,  
Emily Hartman  
U.S. Environmental Protection Agency  
Registration Division  
Herbicide Branch



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number 86004-3	2. EPA Product Manager Kable Bo Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Glycel 41% SL	PM# 25	
5. Name and Address of Applicant (Include ZIP Code) Repar-Glypho, LLC 8070 Georgia Avenue, Suite 209 Silver Spring, MD 20910 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

### Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

- 1) This application is in response to the Agency's Data Deficiency letter dated May 30, 2013 for alternate source of Repar-Glypho, LLC for Glycel 41% SL (EPA Reg. No. 86004-3).
- 2) Please direct all correspondence to: Mandava Associates, LLC; 1050 Connecticut Avenue, NW / Suite 1000; Washington, D.C. 20036.
- 3) The contact person fax number is (202) 223 - 0141 and e-mail address is: mandava@compuserve.com.

### Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name N. Bhushan Mandava	Title Agent for Repar-Glypho, LLC	Telephone No. (include Area Code) 202-223-1424	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received  <b>(Stamped)</b>
2. Signature 	3. Title Agent for Repar-Glypho, LLC		
4. Typed Name N. Bhushan Mandava	5. Date July 1, 2013		

**21-Day Screen of Amendment**  
**(Completed by Contractor)**

21-day Expires on 4-10-13

Document Part Of: 86004-3  
MRID, If Any: 490848

Content Screen: Recommended to  
Pass/Fail

11-3 Review: Passed/Failed/NA

Overall Status: Pass/Fail

Document returned to:

STEPHEN SCHARBLE



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DATA MATRIX

Date 3/18/2013			EPA Reg No./File Symbol 86004-3		Page 1 of 17
Applicant's/Registrant's Name & Address Repar-Glypho, LLC, 8070 Georgia Avenue, Suite 209, Silver Spring, MD 20910			Product Glycel 41% SL		
Ingredient Glyphosate (CAS # 1071-83-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition		Repar-Glypho, LLC, 8070 Georgia Avenue, Suite 209, Silver Spring, MD 20910	OWN	
830.1600	Description of Materials Used to Produce the Product		Repar-Glypho, LLC	OWN	
830.1620	Description of Production Process		Repar-Glypho, LLC	OWN	
830.1650	Description of Formulation Process		Repar-Glypho, LLC	OWN	
830.1670	Discussion of Formation of Impurities		Repar-Glypho, LLC	OWN	
830.1700	Preliminary Analysis		Repar-Glypho, LLC	OWN	
830.1750	Certified Limits		Repar-Glypho, LLC	OWN	
830.1800	Enforcement Analytical Method		Repar-Glypho, LLC	OWN	
830.6302	Color		Repar-Glypho, LLC	OWN	
830.6303	Physical State		Repar-Glypho, LLC	OWN	
830.6304	Odor		Repar-Glypho, LLC	OWN	
830.6313	Stability to Normal & Elevated Temperatures, Metals and Metal Ions		Repar-Glypho, LLC	OWN	
830.6314	Oxidation/Reduction: Chemical Incompatibility		Repar-Glypho, LLC	OWN	
Signature <i>N. B. Mandava</i>			Name and Title N. Bhushan Mandava, Ph.D., Agent for Repar-Glypho, LLC		Date 03/18/2013



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Date 3/18/2013	EPA Reg No./File Symbol 86004-3	Page 2 of 17			
Applicant's/Registrant's Name & Address Repar-Glypho, LLC, 8070 Georgia Avenue, Suite 209, Silver Spring, MD 20910	Product Glycel 41% SL				
Ingredient Glyphosate (CAS # 1071-83-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6315	Flammability		Repar-Glypho, LLC		Not Required
830.6316	Explosibility		Repar-Glypho, LLC		Not Required
830.6317	Storage Stability		Repar-Glypho, LLC	OWN	
830.6319	Miscibility		Repar-Glypho, LLC	OWN	
830.5320	Corrosion Characteristics		Repar-Glypho, LLC	OWN	
830.6321	Dielectric Breakdown Voltage		Repar-Glypho, LLC	OWN	
830.7000	pH		Repar-Glypho, LLC	OWN	
830.7050	UV/Visible Absorption		Repar-Glypho, LLC	OWN	
830.7100	Viscosity		Repar-Glypho, LLC	OWN	
830.7200	Melting Point/Melting Range		Repar-Glypho, LLC	OWN	
830.7220	Boiling Point/Boiling Range		Repar-Glypho, LLC	OWN	
830.7300	Density/Relative Density/Bulk Density		Repar-Glypho, LLC	OWN	
830.7370	Dissociation Constants in Water		Repar-Glypho, LLC	OWN	
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Metho		Repar-Glypho, LLC	OWN	
Signature <i>N. Bhushan Mandava</i>	Name and Title N. Bhushan Mandava, Ph.D., Agent for Repar-Glypho, LLC	Date 03/18/2013			





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Date 3/18/2013	EPA Reg No./File Symbol 86004-3	Page 3 of 17
Applicant's/Registrant's Name & Address Repar-Glypho, LLC, 8070 Georgia Avenue, Suite 209, Silver Spring, MD 20910	Product Glycel 41% SL	

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N. Bhushan Mandava, Ph.D., Agent for Repar-Glypho, LLC

03/18/2013




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Applicant's/Registrant's Name & Address Repar-Glypho, LLC, 8070 Geoargia Avenue, Suite 209, Silver Spring, MD 20910		Product Glycel 41% SL			
Ingredient Glyphosate (CAS # 1071-83-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
CITE-ALL			Syngenta Crop Protection, Inc.	Pay	
			Attn: Regulatory Affairs		
			P.O. BOX 18300		
			Greensboro, NC 27419 (Company # 100)		
			Nufarm Americas, Inc.	Pay	
			150 Harvester Drive, Suite 200		
			Burr Ridge, IL 60527 (Company # 228)		
			The Scotts Company	Pay	
			D/B/A The Ortho Group		
			P.O. BOX 190		
			Marysville, OH 43040 (Company # 239)		
			FMC Corp, Agricultural Products Group	Pay	
			1735 Market Street		
			Philadelphia, PA 19103 (Company # 279)		
Signature 			Name and Title N. Bhushan Mandava, Ph.D., Agent for Repar-Glypho, LLC		Date 03/18/2013




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Date 3/18/2013	EPA Reg No./File Symbol 86004-3	Page 5 of 17			
Applicant's/Registrant's Name & Address Repar-Glypho, LLC, 8070 Georgia Avenue, Suite 209, Silver Spring, MD 20910	Product Glycel 41% SL				
Ingredient Glyphosate (CAS # 1071-83-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
CITE-ALL			E.I. DU PONT DE NEMOURS AND CO., INC	Pay	
			Dupont Crop Protection (S300/427)		
			P.O. BOX 30		
			Newark, DE 19714 (Company # 352)		
			Monsanto Company	Pay	
			1300 I Street, NW, Suite 450 East		
			Washington, DC 20005 (Company # 524)		
			Cheminova A/S	Pay	
			1600 Wilson Blvd., Suite 700		
			Arlington, VA 22209 (Company # 4787)		
			Helena Chemical Co.	Pay	
			225 Schilling Boulevard, Suite 300		
			Collierville, TN 38017 (Company # 5905)		
			Ritter Chemical, Inc. 1550 18th St., N.W., Suite	Pay	
			1000 Washington, DC 20036 (Company #9468)		
Signature 	Name and Title N. Bhushan Mandava, Ph.D., Agent for Repar-Glypho, LLC			Date 03/18/2013	




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Applicant's/Registrant's Name & Address Repar-Glypho, LLC, 8070 Geoargia Avenue, Suite 209, Silver Spring, MD 20910		Product Glycel 41% SL			
Ingredient Glyphosate (CAS # 1071-83-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
CITE-ALL			Drexel Chemical Company	Pay	
			PO BOX 13327		
			Memphis, TN 38113 (Company # 19713)		
			Industria Prodotti Chimici S.P.A.	Pay	
			122 C St., NW, Ste 740		
			Washington, DC 20001 (Company # 33660)		
			Nufarm Limited	Pay	
			P.O. BOX 13439		
			RTP, NC 27709 (Company # 35935)		
			Albaugh, Inc.	Pay	
			P.O. BOX 2127		
			Valdosta, GA 31604 (Company # 42750)		
			BASF Sparks, LLC	Pay	
			P.O. BOX 13528		
			RTP, NC 27709 (Company # 51036)		
Signature 			Name and Title N. Bhushan Mandava, Ph.D., Agent for Repar-Glypho, LLC		Date 03/18/2013

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Ingredient Glyphosate (CAS # 1071-83-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
CITE-ALL			Valent U.S.A. Corporation	Pay	
			1600 Riviera Avenue, Suite 200		
			Walnut Creek, CA 94596 (Company # 59639)		
			Dow AgroSciences, LLC	Pay	
			9330 Zionsville RD 308/2E)		
			Indianapolis, IN 46268 (Company # 62719)		
			Makhteshim-Agan of North America, Inc.	Pay	
			4515 Falls of Neuse RD, Suite 300		
			Raleigh, NC 27603 (Company # 66222)		
			Spray Drift Task Force	Pay	
			Mckenna, Long & Aldridge, LLP		
			1900 K Street, NW		
			Washington, DC 20006 (Company # 66607)		
			Chemingva, Inc. 1600 Wilson Boulevard, Suite	Pay	
			700 Arlington, VA 22209 (Company # 67760)		
Signature 			Name and Title N. Bhushan Mandava, Ph.D., Agent for Repar-Glypho, LLC		Date 03/18/2013




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Applicant's/Registrant's Name & Address Repar-Glypho, LLC, 8070 Geoargia Avenue, Suite 209, Silver Spring, MD 20910		Product Glycel 41% SL			
Ingredient Glyphosate (CAS # 1071-83-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
CITE-ALL			Chemical Products Technologies, LLC	Pay	
			PO BOX 2275		
			Cartersville, GA 30120 (Company # 70829)		
			Nufarm, Inc.	Pay	
			150 Harvester Drive Suite 200		
			Burr Ridge, IL 60527 (Company #71368)		
			Outdoor Residential Exposure Task Force	Pay	
			1350 I Street, N.W.		
			Washington, DC 20005 (Company # 71754)		
			Agricultural Reentry Task Force	Pay	
			1350 I Street, N.W.		
			Washington, DC 20005 (Company # 71755)		
			Nations AG II, LLC	Pay	
			4515 Falls of Neuse Road, Suite 300		
			Raleigh, NC 27609 (Company # 72167)		
Signature 			Name and Title N. Bhushan Mandava, Ph.D., Agent for Repar-Glypho, LLC		Date 03/18/2013




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Applicant's/Registrant's Name & Address Repar-Glypho, LLC, 8070 Georgia Avenue, Suite 209, Silver Spring, MD 20910		Product Glycel 41% SL			
Ingredient Glyphosate (CAS # 1071-83-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
CITE-ALL			Zhejiang Xinan Chemical Industrial Group	Pay	
			115 Obtuse Hill		
			Brookefield, CT 06804 (Company # 73432)		
			FIFRA Endangered Species Task Force, LLC	Pay	
			c/o Harold Himmelman (Beveridge & Diamond		
			PC) 1350 I Street, NW		
			Washington, DC 20005 (Company # 73989)		
			Helm Agro US, Inc.	Pay	
			8295 Tournament Drive, Suite 310		
			Memphis, TN 38125 (Company # 74530)		
			Residential Exposure Joint Venture (REJF)	Pay	
			200 17th Street NW, Suite 300		
			Washington, DC 20006 (Company # 74888)		
Signature 			Name and Title N. Bhushan Mandava, Ph.D., Agent for Repar-Glypho, LLC		Date 03/18/2013

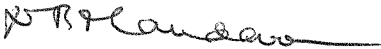


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Applicant's/Registrant's Name & Address Repar-Glypho, LLC, 8070 Geoargia Avenue, Suite 209, Silver Spring, MD 20910		Product Glycel 41% SL			
Ingredient Glyphosate (CAS # 1071-83-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
CITE-ALL			Agricultural Handlers Exposure Task Force	Pay	
			PO BOX 509		
			Macon, MO 63552 (Company # 75234)		
			Mey Corporation	Pay	
			121 S. Estes Drive, Suite 101		
			Chapel Hill, NC 27514 (Company # 80967)		
			Libertas Now, Inc.	Pay	
			108 Severn Ave., Suite B		
			Annapolis, MD 21403 (Company # 81142)		
			AXSS USA, LLC	Pay	
			115 Obtuse Hill Road		
			Brookfield, CT 06804 (Company # 83520)		
Signature 			Name and Title N. Bhushan Mandava, Ph.D., Agent for Repar-Glypho, LLC		Date 03/18/2013





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Ingredient Glyphosate (CAS # 1071-83-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
CITE-ALL			Celsius Property B.V., Amsterdam (NL)	Pay	
			Neuhausen A. RHF Branch		
			4515 Falls of Neuse Rd., Suite 300		
			Raleigh, NC 27609 (Company # 83558)		
			Generic Endangered Species Task Force	Pay	
			(GESTF) 500 Eighth Street, N.W.		
			Washington, DC 20004 (Company # 84653)		
			Red Eagle Chemical Corp	Pay	
			PO Box 640		
			Hockessin, DE 19707 (Company # 85595)		
			Redeagle International LLC	Pay	
			PO Box 640		
			Hockessin, DE 19707 (Company # 85678)		
Signature <i>N. Bhushan Mandava</i>			Name and Title N. Bhushan Mandava, Ph.D., Agent for Repar-Glypho, LLC		Date 03/18/2013




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Ingredient Glyphosate (CAS # 1071-83-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
CITE-ALL			BASF Corporation	Pay	
			P.O. Box 13528/ 26 Davis Drive		
			RTP, NC 27709 (Company # 241)		
			Aceto Agricultural Chemicals Corp	Pay	
			4 Tri Harbor Court		
			Port Washington, NY 11050 (Company #2749)		
			Gowan Company	Pay	
			P.O. Box 5569		
			Yuma, AZ 85366 (Company # 10163)		
			Agan Chem MFG, Ltd.	Pay	
			3120 Highwoods Blvd. Suite 100		
			Raleigh, NC 27604 (Company # 11603)		
			Atanor S.A.	Pay	
			P.O. Box 2127		
			Valdosta, GA 31604 (Company # 46146)		
Signature 			Name and Title N. Bhushan Mandava, Ph.D., Agent for Repar-Glypho, LLC		Date 03/18/2013



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Ingredient Glyphosate (CAS # 1071-83-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
CITE-ALL			Gilmore Marketing and Development	Pay	
			115 Obtuse Hill Road		
			Brookefield, CT 06804 (Company # 65656)		
			United Phosphorus, Inc.	Pay	
			630 Freedom Business Center, Suite 402		
			King of Prussia, PA 19406 (Company # 70506)		
			Bayer Advanced	Pay	
			P.O. Box 12014		
			2 T.W. Alexander Drive		
			RTP, NC 27709 (Company # 72155)		
			Jingma Chemicals Ltd.	Pay	
			P.O. Box 640		
			Hockessin, DE 19707 (Company # 75464)		
Signature <i>N. Bhushan Mandava</i>			Name and Title N. Bhushan Mandava, Ph.D., Agent for Repar-Glypho, LLC		Date 03/18/2013



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 3/18/2013			EPA Reg No./File Symbol 86004-3		Page 14 of 17
Applicant's/Registrant's Name & Address Repar-Glypho, LLC, 8070 Geoargia Avenue, Suite 209, Silver Spring, MD 20910			Product Glycel 41% SL		
Ingredient Glyphosate (CAS # 1071-83-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
CITE-ALL			Agri Packaging & Logistics, Inc.	Pay	
			2503 South Frontage Road		
			Sardis, MS 38666 (Company # 82498)		
			Sharda Worldwide Exports PVT. Ltd.	Pay	
			P.O. Box 640		
			Hockessin, DE 19707 (Company # 82633)		
			PRA Registrations, LLC	Pay	
			P.O. Box 351		
			Voorhees, NJ 08043 (Company # 83173)		
			Sharda USA, LLC	Pay	
			P.O. Box 640		
			Hockessin, DE 19707 (Company # 83529)		
			Tide International, USA, Inc.	Pay	
			4110 136th St. NW		
			Oig Harbor, WA 98332 (Company # 84653)		
Signature <i>N. Bhushan Mandava</i>			Name and Title N. Bhushan Mandava, Ph.D., Agent for Repar-Glypho, LLC		Date 03/18/2013

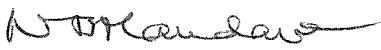


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Applicant's/Registrant's Name & Address Repar-Glypho, LLC, 8070 Geoargia Avenue, Suite 209, Silver Spring, MD 20910		Product Glycel 41% SL			
Ingredient Glyphosate (CAS # 1071-83-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
CITE-ALL			Agsaver II, LLC	Pay	
			4110 1136th St, NW		
			Gig Harbor, WA 98332 (Company # 85806)		
			Glysortia, LLC	Pay	
			4110 136th Street, NW		
			Gig Harbor, WA 98332 (Company # 85998)		
			Texcan Investments & Marketing Company	Pay	
			4110 136th St., NW		
			Gig Harbor, WA 98332 (Company # 86068)		
			Farmway, INC.	Pay	
			P.O. Box 640		
			Hockessin, DE 19707 (Company # 86277)		
			Solar Apex International Limited	Pay	
			P.O. Box 640		
			Hockessin, DE 19707 (Company # 86501)		
Signature 			Name and Title N. Bhushan Mandava, Ph.D., Agent for Repar-Glypho, LLC		Date 03/18/2013




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## DATA MATRIX

Date 3/18/2013		EPA Reg No./File Symbol 86004-3		Page 16 of 17	
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Ingredient Glyphosate (CAS # 1071-83-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
CITE-ALL			Agrilon International, LLC	Pay	
			1300 Corporate Center Curve		
			Eagan, MN 55121 (Company # 86530)		
			USA Chemical, LLC	Pay	
			115 Obtuse Hill Road		
			Brookefield, CT 06804 (Company # 86702)		
			Newagco, Inc.	Pay	
			4110 136th St., NW		
			Gig Harbor, WA 98332 (Company # 86794)		
			Consus Chemicals, LLC	Pay	
			21 Hubble		
			Irvine, CA 92613 (Company # 86828)		
			Cinmax International, LLC	Pay	
			115 Obtuse Hill Rd.		
			Brookefield, CT 06804 (Company # 87659)		
Signature 			Name and Title N. Bhushan Mandava, Ph.D., Agent for Repar-Glypho, LLC		Date 03/18/2013



File  
86004-003-6936  
1B/6.2

4/120

**I. MAIN LABEL FOR FOOD CROP USES**

**GLYCEL 41% SL**

Herbicide

Complete Directions for Use EPA Reg. No. 86004-G

AVOID CONTACT OF HERBICIDE WITH FOLIAGE, GREEN STEMS, EXPOSED NON-WOODY ROOTS OR FRUIT OF CROPS (EXCEPT AS SPECIFIED FOR INDIVIDUAL ROUNDUP READY® CROPS), DESIRABLE PLANTS AND TREES, BECAUSE SEVERE INJURY OR DESTRUCTION MAY RESULT.

Herbicide for Roundup Ready® Crops.

Selective broad-spectrum weed control in Roundup Ready crops. Non-selective, broad-spectrum weed control for many agricultural systems and farmsteads.

Not all products on this label are registered for use in California. Check the registration status of each product in California before using.

Read the entire label before using this product.

Use only according to label instructions.

[Container Label Statement (5 gallons or smaller):]

Do not use this container for residential treatments.

Read the "LIMIT OF WARRANTY AND LIABILITY" statement at the end of the label before buying or using. If terms are not acceptable, return at once unopened.

THIS IS AN END-USE PRODUCT. REPAR-GLYPHO, LLC. DOES NOT INTEND AND HAS NOT REGISTERED IT FOR REFORMULATION. SEE INDIVIDUAL CONTAINER LABEL FOR REPACKAGING LIMITATIONS.

Refillable Container Label Statement:

THIS IS AN END-USE PRODUCT. REPAR-GLYPHO, LLC DOES NOT INTEND AND HAS NOT REGISTERED IT FOR REFORMULATION. IT IS INTENDED THAT REPACKAGING BE ONLY IN ACCORDANCE WITH A REPAR-GLYPHO, LLC REPACKAGING OR TOLL REPACKAGING AGREEMENT.

Non-refillable Container Label Statement:

THIS IS AN END-USE PRODUCT. REPAR-GLYPHO, LLC DOES NOT INTEND AND HAS NOT REGISTERED IT FOR REFORMULATION OR REPACKAGING.



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## 2.0 IMPORTANT PHONE NUMBERS

(To be completed later)

## 3.0 PRECAUTIONARY STATEMENTS

### 3.1 Hazards to Humans and Domestic Animals

**Keep Out of Reach of Children.**

## CAUTION / CUIDADO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

First Aid	
<b>IF IN EYES</b>	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
<b>IF ON SKIN OR CLOTHING</b>	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.
<b>IF SWALLOWED</b>	Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.
<b>IF INHALED</b>	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For Medical Emergency Assistance, call the National Pesticide Information Center 1-800-858-7378.	
<b>NOTE TO PHYSICIAN:</b> No specific antidote. Treat symptomatically. The compound does not cause any definite symptoms that would be diagnostic. Contact with eyes may cause irritation.	

**For chemical emergency: spill, leak, fire, exposure, or accident, call CHEMTREC 1-800-424-9300.**

**DOMESTIC ANIMALS:** This product is considered to be relatively nontoxic to dogs and other domestic animals; however, ingestion of this product or large amounts of freshly sprayed vegetation may result in temporary gastrointestinal irritation (vomiting, diarrhea, colic, etc.). If such symptoms are observed, provide the animal with plenty of fluids to prevent dehydration. Call a veterinarian if symptoms persist for more than 24 hours.

### Personal Protective Equipment (PPE)

**Applicators and other handlers must wear:** long-sleeved shirt and long pants, shoes plus socks, and protective eyewear. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d) (4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.


 United States  
**Environmental Protection Agency**

 Office of Pesticide Programs (7505C)  
 Washington, DC 20460

**Notice of Supplemental Distribution of a Registered Pesticide Product**
**Instructions**

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product

86004-3

Distributor Company Number

69361

**Note: Do not submit distributor product labels**

Name of Registered Product (basic product name accepted by EPA)

Glycel 41% SL

Distributor Product Name

Top Dog Glycel 41% Plus

Name and Address of Distributor (Type; include ZIP code)

 Repar Corporation  
 P.O. Box 4321  
 Silver Spring, MD 20914

**Read All Conditions Before Signing**

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", "distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

**Distributor**

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor

Date

M. Mandel, Agent

4/18/11

**Registrant**

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

Date

M. Mandel, Agent

4/18/11

Please Read All Instructions Before Completing this Form (Form must be typed) Form Approved. OMB No. 2070-0044. Approved Express Mail



# Environmental Protection Agency

Office of Pesticide Programs (7505C)

Washington, DC 20460

## Notice of Supplemental Distribution of a Registered Pesticide Product

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If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product

86004-3

Distributor Company Number

83411

**Note: Do not submit distributor product labels**

Name of Registered Product (basic product name accepted by EPA)

GLYCEL 41% SL

Distributor Product Name

CLEAN FIELD 41 PLUS

Name and Address of Distributor (Type; Include ZIP code)

MID AMERICA MARKETING, INC.  
815 WILL NETT  
FAIRMONT MN 56031  
507/236-2209

### Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
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7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

### Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor

Bruce Davison

BRUCE DAVISON

President

Date

1/13/2010

### Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

Madhu Mandava, Agent for Repar Corp.

M. Mandava

Date

1/18/2010